zimmer

K131129

P.O. Box 708
Warsaw, IN 46581-0708
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510(k) Summary

Applicant:

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AUG 2 0 2013

Contact Person:

Jason Heckaman
Zimmer, Inc.
1800 West Center Street
Warsaw, IN 46580
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Date: 20 August 2013

Trade Name: CAS PSI Shoulder

Common Name: Patient Specific Instruments

Product Code / Device: KWS – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
PBF – Orthopaedic Surgical Planning and Instrument Guides

Classification Name: **21 CFR § 888.3660** – Shoulder joint metal/polymer semi-constrained cemented prosthesis

Predicate Devices: *SurgiCase Orthopaedics, SurgiCase Connect, SurgiCase Guides*, manufactured by Materialise N.V. and cleared under K112389 on 20 July 2012. *Zimmer Patient Specific Instruments System 5.0*, manufactured by Materialise N.V. and cleared under K121640 on 5 Dec 2012. *Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)*, manufactured by Custom Orthopaedic Solutions, Inc. and cleared under K123122 on 5 April 2013.

Device Description:

The CAS PSI Shoulder consists of both software and hardware components and requires the patient to be radiologically scanned.

Device Function, Scientific Concepts, Design Features and Physical Properties that form the Basis for the Device: The CAS PSI Shoulder has been developed with the fundamental goals to assist in pre-operative planning (using the CAS PSI Shoulder Software) and to accurately construct and transfer a pre-operative plan to orthopedic surgical procedures (using the CAS PSI Shoulder Hardware). The hardware (jigs and bone model) have features designed to mate with legally marketed instruments to aid in the implantation of legally marketed Class II implant devices.

Significant Physical Characteristics:
Device Design: The hardware components are designed to mate with legally marketed instruments and thus indirectly aid in the placement of legally marketed implants.
Materials Used: The software is developed in C++ programming language for a windows operating system. The hardware (jigs and bone guide) are made from biocompatible polyamide (Duraform) with press-fit 304 and 17-4 Stainless Steel components.

Comparison to the Predicate:

The subject and predicate devices have similar indications for use and are all intended to aid (either directly or indirectly) in the placement of Class II orthopedic devices. The subject and predicate devices have the same intended use, functioning, patient-specific template design, and use a selective laser sintering manufacturing process for hardware components.

Intended Use:

The CAS PSI Shoulder is intended to be used as a surgical instrument to construct and transfer a pre-surgical plan to orthopaedic surgical procedures.

Indications for Use:

The CAS PSI Shoulder is indicated, based on patient-specific radiological images with identifiable placement anatomical landmarks, to assist in pre-operative planning and/or intra-operative guiding of surgical instruments for shoulder replacement surgical procedures on patients not otherwise precluded from being radiologically scanned.

The CAS PSI Shoulder is to be used with the *Zimmer*® *Trabecular Metal*™ Reverse Shoulder Baseplate in accordance with the implant system's indications and contraindications.

The CAS PSI Shoulder hardware components (jigs and bone model) are intended for single use only.

Performance Data:

Non-Clinical Performance Studies Conducted:

1. Simulated Use Testing
2. Cadaveric Testing
3. Biocompatibility Rationale
4. Sterilization Rationale
5. Dimensional Stability Testing
6. Drop Testing
7. Software Verification and Validation

Non-Clinical Performance Testing Conclusions:
Non-clinical testing demonstrated that the CAS PSI Shoulder meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

Zimmer CAS
% Mr. Jason Heckaman
Manager, Regulatory Affairs
Zimmer, Incorporated
1800 West Center Street
Warsaw, Indiana 46580

Re: K131129
Trade/Device Name: CAS PSI Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, PBF
Dated: July 19, 2013
Received: July 22, 2013

Dear Mr. Heckaman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne -S

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K131129

Device Name:
CAS PSI Shoulder

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131129